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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,753	10/30/2001	Ken Fujise	UTSH:251US	6306

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

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06/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/021,753	Applicant(s) FUJISE ET AL.	
	Examiner J. E. Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,40,46,47,63-66,68-83 and 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,40,63-66,68-70,79-83 and 88 is/are rejected.
- 7) ☒ Claim(s) 46,47 and 71-78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the communication filed on 3/7/08.

The amendment filed 3/7/08 is acknowledged and has been entered.

Claims 39, 40, 46, 47, 63-66, 68-83 and 88 are currently pending in the application and are addressed herein.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 39, 40, 63-66, 68-70, 79-83, 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification must provide adequate written description and evidence of possession of a claimed genus. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must

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convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

The instant claims encompass methods which require assaying Fortilin polypeptide activity either in vitro or in a cell (e.g., see claims 39 and 68). Therefore, the claims encompass a genus of Fortilin activities wherein the genus encompasses all possible Fortilin activities. Thus the claims encompass a genus of Fortilin activities that is indeterminate in size, but could potentially encompass an enormous number of different activities, including Fortilin activities that have not yet been identified. Looking to the specification for the written description of the genus of Fortilin activities encompassed by the claims, it is noted that that the specification discloses that Fortilin binds to p53 polypeptide and Fortilin binds to MCL1 polypeptide which results in Fortilin having the ability to inhibit apoptosis in cells. Thus, the specification has only disclosed as Fortilin activities binding to P53, binding to MCL1 and prevention of apoptosis as the only activities of the Fortilin polypeptide. Thus, these disclosed activities are the only described Fortilin activities which could be measured in the methods of the instant claims. The specification discloses that Fortilin is involved in prevention of apoptosis via p53 and MCL1 binding. The specification does not describe any other Fortilin activity encompassed by the genus of Fortilin activities in the claims, and none are found in the prior art. Therefore, the skilled artisan cannot envision any other Fortilin activity encompassed by the claims, and as such, conception is not achieved until reduction to practice has occurred, regardless of the

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complexity or simplicity of the method of identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. In this case, the activity itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, the only Fortilin polypeptide activities encompassed by the claims which are adequately described in the specification are Fortilin-p53 binding, Fortilin-MCL1 binding, prevention of apoptosis (which also encompasses cell cycle progression).

3. Claims 39, 40, 63-66, 68-70, 79-83, 88 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods wherein the Fortilin activity is Fortilin-p53 binding, Fortilin-MCL1 binding, prevention of apoptosis, and cell cycle progression, does not reasonably provide enablement for the full scope of the claimed methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,

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“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The invention is in a class of invention which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

As indicated above, the claims encompass methods which require assaying Fortilin activity either in vitro or in a cell (e.g., see claims 39 and 68). As such, the claims encompass methods that require assaying a genus of Fortilin activities wherein the genus encompass all possible Fortilin activities, a genus of activities that could encompass an enormous number of different activities, including Fortilin activities that have not yet been identified.

The specification only describes Fortilin binding to p53 polypeptide and Fortilin binding to MCL1 polypeptide as the only activity of the Fortilin polypeptide which could be measured in the instant claims. The specification discloses that Fortilin is involved in prevention of apoptosis via p53 and MCL1 binding. The specification does not describe any other Fortilin activity encompassed by the genus of Fortilin activities in the claims, and none are found in the prior art. Therefore, additional experimentation would be required in order to practice the claimed methods to their full scope. That is, additional experimentation would be required in order to identify Fortilin the activities which could be assayed in the instantly claimed method, other than Fortilin-p53 binding and Fortilin-MCL1 binding. This additional experimentation amounts to

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trial-and-error testing of potential Fortilin activities without guarantee of success. Furthermore, the identification of any other Fortilin activity would amount to a significant and unobvious advance over the state of the art. Therefore, the additional amount of experimentation required to practice the claimed methods to their full scope is considered to be undue.

Response to Arguments

4. Applicant's arguments filed 3/7/08 have been fully considered with respect to the current rejections, but they are not persuasive.

5. Applicants argue that the basis for the written description rejection is the unsupported allegation that the method claims recite "Fortilin activity," which refers to a genus of activity. Applicants contend that there is no evidence or any indication of any activities of Fortilin other than those described in the specification to support the contention that there are activities of Fortilin not described. Applicants assert that it cannot be sufficient to make a rejection based on a completely hypothetical situation--that there *may be* other activities of Fortilin.

In response, it is acknowledged that there is no evidence of *other* Fortilin activity. It is noted that any evidence of another activity would most likely be sufficient to describe that activity. Furthermore, it is respectfully pointed out that the independent claims must, by rule, be larger in scope than the dependent claims. In this case, since the specifically described activities are claimed in dependent claims, the independent claims must encompass activities that are not described. Applicants have not taken issue with assertion that the broad claims encompass activities that are not described by the specification. Rather, Applicants argue that it is improper to make a rejection based on the fact that the claims may encompass activities not described in

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the specification. It is respectfully pointed out that *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) In the instant case, the specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116). Thus, the written description rejection is appropriate.

Applicants also assert that the specification has provided a description of a representative number species to describe the claimed genus.

In response, it is acknowledged that the specification describes Fortilin binding to P53 and MCL1 and has also disclosed that Fortilin can prevent apoptosis. This is not sufficient to adequately describe the genus of activities encompassed by the broad claims. It is noted that limiting the claims to the specifically disclosed activities would obviate the rejection.

With respect to the scope of enablement rejection, Applicants argue that they have described a method of measuring Fortilin's apoptotic activity in Examples 3 and 8, and that binding to p53 and MCL1 could be used to evaluate Fortilin activity. Applicants assert that the action provides no evidence either from the specification or art that even suggests Fortilin may have other activities and the assertion that the skilled artisan would have to practice undue experimentation to determine whether Fortilin has *other* activities is without any basis in the law.

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In response, it is acknowledged that the specification has provided working examples which indicate that Fortilin is capable of inhibiting apoptosis and that Fortilin binds to p53 and MCL1. It is noted that the claims specifically limited to these embodiments are not included in the rejection. Furthermore, as indicated above, the broad claims clearly encompass embodiments which are beyond that which described in the specification. As such, in order for one of skill in the art to practice the claimed method to its full scope, the skilled artisan would have to know which activities beyond those described could be assayed. Therefore, clearly, further experimentation would be required to make and use the claimed invention to its full scope. As indicated above, the additional experimentation required to determine the activities other than those described would amount to undue experimentation.

Therefore, Applicants arguments are not persuasive.

Claim Objections

6. Claims 46, 47, 71-78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635